In The United States Court of Federal Claims

No. 99-552V

(Filed: October 31, 2011)

Reissued: November 15, 2011[1]

ELIZABETH SHAPIRO,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* Vaccine case; Petition for review; Hepatitis-
* B vaccination; Standard of review;
* Hypothyroidism; Finding that
* hypothyroidism predated vaccination was
* arbitrary and capricious; Misapplication of
* "contemporaneous record" rule; Failure to
* explain or otherwise account for
* contradiction in medical record as to critical
* fact; Systemic Lupus Erythematosus; Failure
* to show proximate temporal relationship
* between the vaccination and the onset of
* illness; Remand.
*

OPINION

Clifford John Shoemaker, Shoemaker and Associates, for petitioner.

Heather Lynn Pearlman, United States Department of Justice, Washington, D.C., with whom was Assistant Attorney General *Tony West*, for respondent.

ALLEGRA, Judge:

Petitioner, Elizabeth Shapiro, seeks review of a decision issued by Special Master Christian Moran denying her petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 300aa-34 (2006), alleging that she suffers from hypothyroidism and Systemic Lupus

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[1] An unredacted version of this opinion was issued under seal on October 31, 2011. The parties were given an opportunity to propose redactions, but no such proposals were made. Nonetheless, the court has incorporated some minor changes into this opinion.

Erythematosus (SLE) as a result of hepatitis-B vaccinations that she received. On review, Special Master Moran denied compensation, finding that Ms. Shapiro's illnesses were not caused by the hepatitis-B vaccinations. For the reasons that follow, this court affirms, in part, and reverses, in part, that decision.

I. BACKGROUND

A brief recitation of the facts provides necessary context.

Petitioner was born in 1950 and is a nurse-practitioner. She has three children and her husband is a pediatrician. The record contains no contemporaneous medical records suggesting that petitioner had either of the illnesses in question prior to receiving her first hepatitis-B vaccination in 1992. The record reflects that petitioner's only medical visits before the vaccinations were routine checkups with Dr. Sylvan Frieman, her gynecologist. Dr. Frieman submitted statements for the record indicating that petitioner was healthy prior to receiving the vaccinations in question. Petitioner's employer, Dr. Kenneth Klebanow, filed a similar statement.

On April 13, 1992, petitioner received the first of three hepatitis-B vaccinations. On April 29, 1992, she visited Dr. Frieman and reported abdominal bloating and weight gain. Dr. Frieman's records do not reflect when these symptoms began.

On September 21, 1992, petitioner received her second hepatitis-B vaccination. On October 19, 1992, she visited Dr. Richard Berg, an internist and infectious disease specialist, complaining of a five-day history of severe headache and neck ache; lightheadedness; a rapid, irregular heartbeat; and an extended menstrual period.[2] That same day, testing revealed that petitioner's thyroid stimulating hormone was ten times the normal level, a result indicative of hypothyroidism. On October 21, 1992, Dr. Berg prescribed Synthroid to treat petitioner's hypothyroidism. Notes from a follow-up visit with Dr. Berg that occurred approximately one month later indicate that petitioner's palpitations and lightheadedness had abated and that her menstrual period had improved.

On February 8, 1993, petitioner received her third and final hepatitis-B vaccination. Petitioner returned to Dr. Berg twice in March of 1993, complaining of worsening symptoms, and reporting palpitations, nausea and abdominal pain. Dr. Berg adjusted petitioner's dosage of Synthroid and referred her back to Dr. Frieman, as well as to a new doctor, Dr. Ronald L. Ginsburg, a gastroenterologist. Petitioner visited Dr. Ginsberg in April of 1993, complaining of constipation, weight gain, prolonged menstrual periods, palpitations and lightheadedness.

[2] According to petitioner's affidavit, she did not have an internist at the time she received her second vaccination. Following that vaccination, her employer, Dr. Klebanow, felt that she needed to be seen by a doctor with some immediacy, but the doctor to whom he referred petitioner was not taking new patients. Thereafter, a friend referred petitioner to Dr. Berg.

Shortly after this visit, Dr. Ginsberg wrote Dr. Berg, summarizing his observations. In that letter, which was dated April 22, 1993, Dr. Ginsberg stated –

> [Ms. Shapiro] dates the onset of her current illness to about October of 1991 with progressively worsening constipation for the next approximately year. She also suffered a certain amount of weight gain and finally, had rather prolonged menstrual periods. In addition, she developed palpitations and a lightheadedness and a very slow pulse rate for her, between 48-60. She began feeling chest pressure and at that point was seen [by Dr. Berg].

Although this passage of the letter suggested that petitioner's symptoms began before her first hepatitis-B vaccination, that notion is contradicted at a later point in the same letter. On the second page of his letter, Dr. Ginsberg wrote: "[i]nterestingly, [Ms. Shapiro] notes that she had hepatitis-B vaccine which was done about a few weeks before she began having her initial problem, and then a booster which was a few weeks before her recurrent problem." Because petitioner had her first hepatitis-B vaccination on April 13, 1992, this second statement suggests that petitioner's "initial symptoms" began in late April of 1992.

On July 23, 1993, petitioner filed an incident report with the Vaccine Adverse Event Reporting System in which she indicated that her symptoms first occurred after her first hepatitis-B immunization. From that point on, petitioner's medical records consistently reflect that, in providing her medical history on a half a dozen or more occasions, she told her doctors that her symptoms began after her first vaccination.[3]

At or about the time she filed her incident report, petitioner asserts that she began experiencing symptoms associated with SLE. On July 7, 1993, she saw Dr. Harvey Schonwald, a urologist, due to what she believed were symptoms of hematuria – the presence of red blood cells in her urine. Dr. Schonwald's records indicate that she had been experiencing this symptom for approximately two months. A cystoscopy (an endoscopy of the urinary bladder) taken at this time did not reveal the source of the hematuria. On a July 28, 1993, visit with Dr. Berg, petitioner also mentioned having joint pain. More than a year later, on August 2, 1994, petitioner had an antinuclear antibody test which was positive, another indication of SLE. Throughout this period, petitioner visited Dr. Joyce Burd, a rheumatologist, who catalogued petitioner's many symptoms. On September 2, 1994, Dr. Burd wrote that petitioner "probably" had SLE, the first mention of this disease in any medical record. From this point forward, petitioner's health deteriorated. Hundreds of pages of records demonstrate that she has continued to experience ill health up to and including the present time.

[3] For example, on July 28, 1993, petitioner told Dr. Berg that her nausea and palpitations began two weeks after her first vaccine. On October 21, 1993, she told her dentist, Dr. Robert Minch, that she had an autoimmune reaction to her hepatitis-B vaccination. As reflected in other medical records, petitioner made similar statements to Dr. Joyce Burd, a rheumatologist, and Dr. Daniel Drachman, a neurologist, on September 2, 1994, and November 1, 1994, respectively.

On August 2, 1999, petitioner filed her vaccine petition. In April of 2000, the special master originally assigned to this matter stayed the case, apparently hoping it would be settled under a global resolution of numerous hepatitis-B cases filed at or around that time. That settlement, however, never materialized.

Subsequently, petitioner filed several sets of medical records and a number of expert reports. Among those opinions was one from Dr. Joseph Bellanti, rendered in June 2006. Dr. Bellanti opined that Ms. Shapiro's symptoms worsened after each dose of the hepatitis-B vaccination, a causation pattern known as "challenge-rechallenge." He opined that this sequence of adverse reactions resulted in the development of SLE. On January 8, 2007, Ms. Shapiro filed a report by a second expert, Dr. Yehuda Shoenfield, who serves as the head of the Center for Autoimmune Diseases at Sheba Medical Center, Tel-Aviv University, Israel.[4] Dr. Shoenfield opined that Ms. Shapiro likely had a genetic predisposition to develop autoimmune diseases and that the hepatitis-B vaccine triggered her autoimmune condition. Dr. Shoenfeld linked the three hepatitis-B vaccinations received by Ms. Shapiro to her development of thyroid disease and SLE. For its part, respondent provided expert reports from two doctors, Dr. Alan Brenner and Dr. Brian Ward. Both concluded that there was no association between Ms. Shapiro's medical conditions and her receipt of the hepatitis-B vaccine.

For reasons unexplained, there was no activity whatsoever in this case for more than three and a half years – from August 2, 2002, through February 8, 2006. On July 30, 2007, the case was reassigned to Special Master Moran. The Special Master thereafter conducted two hearings in the case – on November 24, 2008, and January 8, 2009, respectively. At the first of these hearings, Ms. Shapiro and Dr. Shoenfeld testified in person; at the second, Dr. Ward testified in person. Subsequent to these hearings, Ms. Shapiro was permitted to file additional evidence and medical literature in support of her case.

On April 27, 2011, the Special Master issued his decision denying petitioner's claim. *Shapiro*, 2011 WL 1897650. In that decision, the Special Master rejected the opinions of petitioner's experts, observing that they had relied on assertions made by Ms. Shapiro that she was healthy prior to 1992. Although Ms. Shapiro had reaffirmed these assertions in affidavits filed in the case, the Special Master concluded that "[a] record created much closer in time supports a different finding." *Id*. at *6. In this regard he found that –

> A preponderance of evidence supports a finding that Ms. Shapiro was having health problems before 1992. In April 1993, Ms. Shapiro saw a gastroenterologist, Dr. Ginsberg, who obtained a history from her.

[4] As noted by the Special Master in his opinion, Dr. Shoenfeld "has written more than 1,500 articles in peer-reviewed journals and more than 20 books, one of which includes the 'first trial in the world to compile the diagnostic criteria for more than 100 different autoimmune diseases.' Dr. Shoenfeld also served as editor and founder of the journal, Autoimmunity Reviews." *Shapiro v. Sec'y of Health and Human Servs.*, 2011 WL 1897650, at *2 (Fed. Cl. Apr. 27, 2011).

> Dr. Ginsberg's record dates the onset of Ms. Shapiro's condition to "about October of 1991." He notes that Ms. Shapiro experienced progressively worsening constipation, weight gain, and prolonged menstrual periods during the following year. Dr. Ginsberg also recounts that Ms. Shapiro developed palpitations, lightheadedness, and a slow pulse rate (although he does not indicate when she develops these symptoms).
>
> Thus, there is a conflict between Dr. Ginsberg's record and Ms. Shapiro's affidavit. Dr. Ginsberg's 1993 note records that she was having constipation and other problems since October 1991. In contrast, Ms. Shapiro stated that before 1992, she was "very healthy." Ms. Shapiro made this assertion in 2006, which is more than 10 years after the events in question. Ms. Shapiro has not persuasively explained why her recollection of these distant events is more accurate than the information she provided to Dr. Ginsberg in 1993. Given the circumstances, Dr. Ginsberg's record is more probative.

Id. (footnote and citations omitted).[5] Cementing further his views regarding the record, the Special Master observed –

> As discussed below, the finding that a preponderance of evidence shows that Ms. Shapiro suffered constipation, weight gain, and menstrual irregularities in 1991 is very important to resolving her thyroid claim. The experts explained the significance of menstrual irregularities, constipation, and weight gain. Dr. Ward stated that menstrual irregularities, constipation, and weight gain, are common symptoms for hypothyroidism. According to Dr. Ward, these symptoms could have been "abstracted from a textbook description of hypothyroidism." Dr. Shoenfeld, like Dr. Ward, agrees that Ms. Shapiro's initial symptoms were indicative of a hypothyroid condition.

Id. (citations omitted).

Later in his opinion, the Special Master addressed *seriatim* petitioner's claims regarding her thyroid problems and SLE. As to her hypothyroidism, the Special Master concluded that –

> The experts agreed that gaining weight, having constipation, and having menstrual irregularities are symptoms of a hypothyroid condition. When Ms.

[5] Although not noted in the Special Master's decision, Dr. Ward focused upon Dr. Ginsberg's letter in a supplemental report that he filed on September 28, 2009. That report discounted the notion that the reference to "October of 1991" was a typographical error propagated by Dr. Ginsberg's transcription service and should have read instead "October of 1992." Dr. Ward pointed out that Ms. Shapiro's other medical records contradicted the notion that the onset of her symptoms occurred on the latter date.

> Shapiro started having these problems is a question of fact. Here, a preponderance of the evidence supports a finding that Ms. Shapiro was gaining weight, having constipation, and having menstrual problems beginning around October 1991. The evidence supporting this finding is summarized in section II.B. Thus, a preponderance of evidence supports a finding that Ms. Shapiro's thyroid problems began in approximately October 1991.

Id. at 13 (citations omitted). The only evidence "summarized in section II.B" of the Special Master's opinion "supporting [the] finding" that Ms. Shapiro's problems "began in approximately October 1991" was the aforementioned letter by Dr. Ginsberg. *Compare id.* at *6 *with id*. at *13. The Special Master concluded his brief analysis of the thyroid issue by stating that "[a] finding that Ms. Shapiro's thyroid problems began before she first received the hepatitis-B vaccine resolves Ms. Shapiro's claim that the hepatitis-B vaccine caused her thyroid condition," adding that "[b]ecause Ms. Shapiro was afflicted with a thyroid condition before she received the hepatitis-B vaccine, the vaccine could not have caused the disease." *Id.*

As to Ms. Shapiro's SLE claim, the Special Master noted that proof of that claim required evidence of a temporal relationship between the administering of the vaccine and the onset of Mr. Shapiro's SLE symptoms. The Special Master first reviewed the medical literature and Dr. Shoenfeld's testimony and concluded, based thereupon, that the timeframe in which it was "medically acceptable to infer causation" was two to three weeks, that is to say, this was the period within which exposure to any antigen in the vaccine should have produced symptoms. *Id*. at *14. The Special Master then found that petitioner's symptoms did not onset within this interval. He noted that petitioner's second and third doses of the vaccine were administered on September 21, 1992, and February 8, 1993, respectively. He further noted that the two symptoms that Dr. Shoenfeld testified had heralded the onset of the SLE did not arise until July of 1993 – as documented by medical reports from Drs. Berg and Schonwald – too late to fall within the period expected. The Special Master found, relying upon the expert report of Dr. Ward, that the remainder of the symptoms petitioner experienced "immediately following her first and second doses of the hepatitis B vaccine are compatible with hypothyroidism." *Id*. Based on these findings, the Special Master concluded that Ms. Shapiro had failed "to establish a 'showing of a proximate temporal relationship between vaccination and injury.'" *Id*. at *13 (quoting *Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Summarizing, the Special Master concluded his decision, as follows:

> Ms. Shapiro presented a theory for compensation asserting that her thyroid disease began after her April 1992 hepatitis B vaccination. This theory is not supported because a preponderance of the evidence establishes that Ms. Shapiro suffered from a thyroid dysfunction before she received her first vaccination in April 1992. Because Ms. Shapiro's thyroid problems began before she received her first hepatitis B vaccination, the vaccine did not cause her thyroid condition.

> Ms. Shapiro's second theory for compensation asserted that she developed SLE within three weeks after her second dose or third dose of the hepatitis B vaccine. Ms. Shapiro has established that a medically appropriate interval for the development of SLE is within three weeks of a vaccination. But, Ms. Shapiro did not experience problems linked to SLE within three weeks following her second or third dose. Although the record shows that Ms. Shapiro may have developed SLE, this onset was outside the time expected by medical science.

On this basis, he found that "Ms. Shapiro is not entitled to compensation for her thyroid condition or SLE." *Id*.

On May 27, 2011, petitioner filed a motion to review the Special Master's decision. On June 27, 2011, respondent filed its response to the motion. On September 22, 2011, this court held oral argument on the motion.

II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: "(A) uphold the findings of fact and conclusions of law . . . ; (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or; (C) remand the petition to the special master for further action in accordance with the court's direction." *Id*. at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health and Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec'y of Health and Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

Within this framework, petitioner makes two banner claims. First, she asserts that the Special Master premised his rejection of her hypothyroidism claim on an arbitrary and capricious finding – *to wit*, that a preponderance of the evidence showed that she suffered from that condition prior to receiving the first of her three hepatitis-B vaccinations. Next, she contends that the Special Master erred in rejecting her SLE claim by failing to recognize that her symptoms arose during the medically appropriate interval for the development of SLE. The court will consider these claims in turn.

A. Hypothyroidism

Special Master Moran rejected petitioner's claim that she developed hypothyroidism as an adverse reaction to the hepatitis-B vaccine because he found that this condition predated her first dose of that vaccine. In reaching the latter finding, the Special Master discounted the affidavits and testimony of several individuals, including petitioner and her doctor employer, that she had been well prior to the vaccination. He chose to rely instead solely upon a letter sent from Dr. Ginsberg to Dr. Berg in which the former described the onset of petitioner's condition as

occurring in "about October of 1991." That date, of course, is significant, as petitioner did not receive her first dose of the vaccine until six months later, on April 13, 1992.

The Special Master found that there was "a conflict between Dr. Ginsberg's record and Ms. Shapiro's affidavit," *Shapiro*, 2011 WL 1897650, at *6, and that petitioner had "not persuasively explained why her recollection of these distant events is more accurate then [sic] the information she provided to Dr. Ginsberg in 1993." *Id.*[6] Indeed, at a half a dozen critical junctures in his decision, in explaining the basis for various findings, the Special Master returned to Dr. Ginsberg's letter, alternatively characterizing it as: representing "a preponderance of evidence" in favor of a finding that the onset of petitioner's symptoms was in October 1991, *id*. at *6 and *13; "not support[ing] Ms. Shapiro's or Dr. Frieman's recollection of the onset of these symptoms," *id*. at *7; contradicting various medical histories reflected in other doctors' records in 1992 and 1994, *id*. at *7 (Dr. Frieman) and *11 (Dr. Drachman); and "support[ing] a finding that Ms. Shapiro's thyroid problems began in approximately October 1991, *id*. at *13. Again and again, the Special Master returned to Dr. Ginsberg's letter, repeatedly using it as a factual fulcrum on which to leverage his findings – treating it as if it were contemporaneous evidence that contradicted petitioner's claims. This approach might be sound were it not for two problems: the letter was neither contemporaneous nor contradictory.

There is little doubt that the decisional law in the vaccine area favors medical records created contemporaneously with the events they describe over subsequent recollections. *See Cucuras v. Sec'y of Health and Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *see also Burns by Burns v. Sec'y of Health and Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).[7] These vaccine cases often take their lead from *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948), an antitrust case in which the Supreme Court reversed a district court finding that had discounted the content of contemporaneous documents based on the testimony, years later, of the documents' authors. Explaining its reasoning, the Supreme Court stated that "[w]here such testimony is in conflict with contemporaneous documents we can give it little weight." 333 U.S. at 396; *see also Montgomery Coca-Cola Bottling Co. v. United States*, 622 F.2d 1318, 1328 (Ct. Cl. 1980). In the vaccine context, contemporary medical records are considered trustworthy because they "contain information supplied to or by health professional to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528. "With proper treatment hanging in the

[6] Notably, on this point, the Special Master indicated that "[t]he finding that Ms. Shapiro's testimony is not accurate should not be interpreted as a suggestion that Ms. Shapiro deliberately was dishonest. Instead, the passage of time is likely to have mixed the sequence of events in Ms. Shapiro's recollection." *Shapiro*, 2011 WL 1897650, at *6 n.5.

[7] The Federal Circuit has also repeatedly relied upon this principle in unpublished affirmances of Special Master decisions. *See McGinley v. Sec'y of Health and Human Servs.*, 194 F.3d 1337, at *3 (Fed. Cir. 1999) (table); *Mowen v. Sec'y of Health and Human Servs.*, 70 F.3d 1290 (Fed. Cir. 1995) (table); *Aea v. Sec'y of Health and Human Servs.*, 6 F.3d 787 (Fed. Cir. 1993) (table); *Bingham by and through Bingham v. Sec'y of Health and Human Servs.*, 960 F.2d 156 (Fed. Cir. 1992) (table).

balance," the Federal Circuit has stated, "accuracy has an extra premium." *Id*. at 1528; *see also Andreau ex rel. Andreau v. Sec'y of Health and Human Services*, 569 F.3d 1367, 1383 (Fed. Cir. 2009). For this reason, this court has not hesitated to give such contemporaneous medical documents credence over oral testimony adduced years later. *See Doe v. Sec'y of Health and Human Servs.*, 95 Fed. Cl. 598, 607 (2010); *Moberly ex rel. Moberly v. Sec'y of Health and Human Servs.*, 85 Fed. Cl. 571, 595 (2009), *aff'd*, 592 F.3d 1315 (Fed. Cir. 2010); *Murphy v. Sec'y of Health and Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. denied*, 506 U.S. 974 (1992).

"But like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking." *Campbell ex. rel. Campbell v. Sec'y of Health and Human Servs.*, 69 Fed. Cl. 775, 779 (2006) . As this court has aptly observed:

> It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight. . . . That rule has been followed in Program cases. . . . The rule should not be applied blindly, however. Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent. Records which are incomplete may be entitled to less weight than records which are complete. If a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account. Further, it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy, 23 Cl. Ct. at 733 (quoting *Clark v. Sec'y of Health and Human Servs.*, 1991 WL 57051 (Cl. Ct. Spec. Mstr. March 28, 1991)); *see also Campbell*, 69 Fed. Cl. at 779; *Camery v. Sec'y of Health and Human Servs.*, 42 Fed. Cl. 381, 391 (1998).[8] Logic and a few cases suggest that the special weight given an earlier record of an event over a later one diminishes when the first record is made some time after the event recorded; ought to diminish further when the time interval between two *post hoc* records is slight; and should all but disappear where the records are both *post hoc*, created within a short time of each other, and come with the same badges of reliability. *See, e.g.*, *Lawson v. United States*, 454 F. Supp. 2d 373, 388 n.20 (D. Md. 2006) (in Federal Tort Claims Act case, distinguishing *U.S. Gypsum* and *Cucuras* where the conflict was largely between medical records generated at about the same time); *Conner v. Sec'y of Health and Human Servs.*, 2011 WL 3648603, at *3 (Fed. Cl. Spec. Mstr. July 26, 2011); *see also*

[8] *See also Ale v. Tenn. Valley Auth.*, 269 F.3d 680, 689 (6th Cir. 2001) (*U.S. Gypsum* rule inapplicable where documentary evidence was not "unambiguous," but rather "vague"); *Riddell v. Guggenheim*, 281 F.2d 836, 840 (9th Cir. 1960) (same where documentary evidence was "equivocal").

Cueller v. Joyce, 596 F.3d 505, 511 (9th Cir. 2010); *Capobres v. Astrue*, 2011 WL 1114256, at *5 (D. Id. Mar. 25, 2011).[9]

These various limitations suggest that a court ought to proceed cautiously before allowing the calendar to drive its choice between two competing documents. Reflexively invoking the "contemporaneous record" rule and other evidentiary principles based on when a record is created without observing the practical limitations on their use can hinder rather than promote the accuracy of the fact-finding process. Indeed, the rigid application of such timing provisions can quickly lead to arbitrary findings if, *inter alia*, the fact-finder treats a record as contemporaneous when it is not, or ascribes determinative significance to a slight difference in the timing of the creation of two records generated under similar circumstances. It is in both these regards that the Special Master went amiss here.

Throughout his opinion, the Special Master seemed to ignore the fact that the portion of Dr. Ginsberg's letter on which he relied was in no sense contemporaneous, at least as that term is ordinarily understood and applied by the courts. "Contemporaneous denotes a matter that "originat[es], exist[a], or happen[s] during the same time period," Am. Heritage Dictionary 396 (4th ed. 2000); *see also* III The Oxford Dictionary 812 (2d ed. 1998) ("[b]elonging to the same time or period; existing or occurring at the same time"). Events thus are "contemporaneous" if they arise roughly during the same time period and are thereby marked by characteristics compatible with that origin.[10] It is in this natural sense of the word that courts, including the

[9] Conversely, logic and cases suggest that the longer the interval between the records, the more reliable the position occupied by the recordation made closer in time to the event recorded. *See, e.g.*, *Passamaquoddy Tribe v. United States*, 82 Fed. Cl. 257, 273 (2008), *aff'd*, 426 Fed. Appx. 916 (Fed. Cir. 2011) ("a court may consider earlier testimony or commentary [by the same witness] to be more credible than testimony or commentary that is produced further along in the course of litigation"); *Alaska Pulp Corp., Inc. v. United States*, 59 Fed. Cl. 400, 405-06 (2004) ("relying on recorded remarks and early correspondence [of a corporate officer] [as] much more credible . . . than later evidence attributed to him").

[10] *See Dimuzio v. Resolution Trust Corp.*, 68 F.3d 777, 783 n.5 (3d Cir. 1995); *In re Stephens*, 242 B.R. 508, 511 n.2 (Bankr. D. Kan. 1999); *In re Arctic Air Conditioning, Inc.*, 35 B.R. 107, 109 (Bankr. Tenn. 1983). A variety of decisions comport with this natural reading of the term, with most interpretations holding that events are contemporaneous if arising within hours or days, but not months or years apart. *See, e.g.*, *Williams v. United Parcel Serv., Inc.*, 2006 WL 2472896, at *4 (W.D. Okla. Aug. 23, 2006) (medical examination was contemporaneous even though accident occurred approximately two hours earlier); *State v. Crisp*, 629 S.W.2d 475, 479 (Mo. Ct. App. 1981) ("It is not common sense to say that events that happened almost three years apart were reasonably contemporaneous."); *Spring Garden Mut. Ins. Co. v. Evans*, 15 Md. 54 (1860) (recollection recorded five months after event not contemporaneous); *In re Adelphia Automatic Sprinkler Co.*, 184 B.R. 224, 227 n.4 (E.D. Pa. 1995) (lease extension agreement signed twenty-five days after payment made represented a substantially contemporaneous exchange); *In re Independence Land Title Corp. of Ill.*, 9 B.R. 394, 396 (Bankr. N.D. Ill. 1981) (loan and perfection of security interest were not

Federal Circuit, have treated as "contemporaneous" those medical records that are generated at or around the time that the symptoms are being experienced and reported. *See, e.g.*, *Cucuras*, 993 F.2d at 1528. Here, however, the Special Master gave effect to a medical history created approximately a year after the symptoms were first experienced as if it were contemporaneous. That treatment was inaccurate and ultimately misleading. *Cf. Baglio v. Sec'y of Health and Human Servs.*, 2005 WL 6117471 at *16 n.32 (Fed. Cl. June 3, 2005) (in which the same Special Master indicated that it was "somewhat problematic to label records created two months later as 'contemporaneous'"). In particular, it led the Special Master to invoke (*see Shapiro*, 2011 WL 1897650, at *6) principles from cases like *Burns* and *Cucuras* that simply are inapposite here.

Along this faulty decisional path, the Special Master wielded the principle favoring contemporaneous records to discount not only testimony and affidavits produced more than a decade after the medical events described,[11] but also other medical histories taken down by medical professionals a couple of months after Dr. Ginsberg's letter was generated. The Special Master thus proceeded as if he were comparing a recordation made close in time to the event described to others made years later. In fact, though, this case involved multiple recordations made one to two years after Ms. Shapiro received her first vaccination – all of which were created by treating physicians under similar circumstances, with Ms. Shapiro's "proper treatment hanging in the balance." *Cucuras*, 993 F.2d at 1528. There is no indication – certainly none in the decisional law – that the evidentiary principle tending to give more credence to records created closer in time to the experiences recorded can be applied so finely. In terms of reliability, then, it would appear that the Special Master departed from the law in his somewhat pedantic use of the calendar – on one hand, giving the Ginsberg letter too much credit, and on the other, failing to account for the relatively slight differences in the respective timing of that letter and the subsequent medical histories. Moreover, the Special Master entirely ignored the fact that these subsequent medical histories all reinforced each other in reflecting that the hypothyroidism symptoms arose after the first vaccination.

"contemporaneous" where separated by two months). An old Alabama case summarizes well the evidentiary considerations that go into these formulations, stating that –

> To be contemporaneous, the declaration need not be at the exact same time, but must be so proximate in point of time as to grow out of, elucidate, and explain the character and quality of the main fact, and must be so closely connected with it as to virtually constitute but one entire transaction, and to receive support and credit from the principal act sought to be thus elucidated and explained.

Bessierre v. Alabama City, G&A Ry. Co., 179 Ala. 317 (Ala. 1912) (quoting *Hawk's Case*, 72 Ala. 112, 117-18 (Ala. 1882)).

[11] Some might find it ironic for the Special Master to discount so severely the more recent evidence adduced by Ms. Shapiro as being outdated, without accounting for the nine plus years that her case was in the Vaccine Program before receiving a hearing. Of course, most of that time elapsed before the case was transferred to the Special Master.

But, there is an even more fundamental problem with how the Special Master wielded Dr. Ginsberg's letter in making his fact findings – one that in many ways dwarfs the problems iterated so far. And that problem is this: Not once, in his half dozen or so references to this letter did the Special Master note that the second page of the letter contained a passage that supports petitioner's version of the facts. That second page – hard to miss as it is only three short paragraphs below the reference to the "October 1991" onset – indicated that "[i]nterestingly, [Ms. Shapiro] notes that she had hepatitis-B vaccine which was done about a few weeks before she began having her initial problem, and then a booster which was a few weeks before her recurrent problem." Now it would be one thing if the Special Master had weighed this statement against Dr. Ginsberg's prior reference to "October of 1991" and found, based on the record as a whole, the latter view more accurate. But, the Special Master did not do this. Indeed, when he referred to "preponderant evidence" as supporting the early onset of petitioner's symptoms the only document he cited was Dr. Ginsberg's letter – and, as it turns out, he was only citing the first page of that document. In the court's view, the Special Master was not at liberty to don blinders to the portion of the letter that contradicted his findings and then to use his selective reading to shred other evidence originating near the same time as the letter that supported petitioner's view that her symptoms did not arise until after the administration of the vaccine.

The Special Master's defective approach in this regard cinches the court's view that his findings regarding petitioner's hypothyroidism claim are arbitrary and capricious. To be sure, a finder of fact generally is not required to itemize every piece of evidence on an issue and adopt or reject it. *See, e.g.*, *Leisch v. United States*, 612 F.3d 975, 981 (8th Cir. 2010); *Reich v. Newspapers of New England*, 44 F.3d 1060, 1079 (1st Cir. 1995). And this undoubtedly is true in vaccine cases. *See Whitecotton, by Whitecotton v. Sec'y of Health and Human Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996); *Hodges v. Sec'y of Health and Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). But, this principle is no license to ignore entirely significant evidence that contradicts a finding. Rather, consistent with the duties imposed by the Vaccine Act, the task of a Special Master is to "consider[] the relevant evidence in the record as a whole, draw[] plausible inferences and articulate[] a basis for his decision which is rational." *Hines v. Sec'y of Health and Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1348 (Fed. Cir. 2010); *Lampe*, 219 F.3d at 1360; *Snyder ex rel. Snyder v. Sec'y of Health and Humans Servs.*, 88 Fed. Cl. 706, 718 (2009); *see also* Rule 8(b), Vaccine Rules of the Office of Special Masters (special master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties"). And the Special Master did not adequately discharge this duty in considering petitioner's hypothyroidism claim.[12]

[12] Various courts have found that the rejection of insurance claims by plan administrators based on "selective readings" of the evidence "that are not reasonably consistent with the entire picture" is a "hallmark of an arbitrary and capricious decision." *Holmstrom v. Metropolitan Life Ins. Co.*, 615 F.3d 758, 777 (7th Cir. 2010); *see also Majeski v. Metropolitan Life Ins. Co.*, 590 F.3d 478, 483-84 (7th Cir. 2009) (holding that denial decision was arbitrary, where insurer selectively relied on pieces of evidence to support denial of benefits, while that evidence in

The inconsistencies in Dr. Ginsberg's letter obliged the Special Master to look elsewhere to resolve the hypothyroidism issue. As was said above, "[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health and Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 126 (Fed. Cir. 1992); *see also Campbell*, 69 Fed. Cl. at 779. And, as it turns out, there is evidence in the record that favors petitioner's rendering of the facts. For one thing, there are no medical records suggesting that petitioner visited any doctor in or about October 1991, complaining about the symptoms in question.[13] The fact that such records were not produced does not mean, of course, that such visits did not occur. Yet, a finding that petitioner did not see a doctor about her hypothyroidism symptoms until after her first hepatitis-B immunization is supported by the affidavit of her employer, himself a medical doctor, who indicated that, after her first vaccination, she sought out his recommendation as to the name of an internist when she began experiencing these symptoms. That recommendation, of course, would have been unnecessary had petitioner seen an internist about the same symptoms six months earlier, in October 1991. It bears mention, moreover, that the same employer swore that petitioner did not begin to experience symptoms until after she received her first vaccination. That claim is supported by notes of symptoms taken by Dr. Frieman when Ms. Shapiro visited his office on April 29, 1992 – a truly contemporaneous record made sixteen days after petitioner received her first dose of the vaccine. Finally, there are the other medical histories taken in 1993

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context demonstrated disability); *Glenn v. Metropolitan Life Ins. Co.*, 461 F.3d 660, 672-74 & n.4 (6th Cir. 2006) (holding denial decision was arbitrary where plan selectively considered evidence to reach decision unsupported by the record as a whole), *aff'd*, 554 U.S. 105 (2008) (approving Sixth Circuit's reasoning). In one decision in this line, a district court criticized a plan administrator's "selective reading of the administrative record" because of "its use of several sentences of a report . . . without addressing the doctor's conclusion in that same report" that contradicted the selective reading. *Thorpe v. Continental Cas. Co.*, 2002 WL 31845876, at *5 (E.D. Pa. 2002).

[13] Interestingly, earlier in his opinion, the Special Master wrote –

> Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the problems of the patient. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all of their problems to the doctor. Third, having heard about the symptoms, the doctor records what he (or she) was told.

Shapiro, 2011 WL 1897650 at * 4. While the court questions the accuracy of this statement as an evidentiary standard, it appears that the Special Master did not apply it consistently in this case. Thus, he seemed to overlook the fact that, inconsistent with the first of the three propositions listed above, there was no record indicating that Ms. Shapiro saw a medical professional in October 1991, when, according to the Special Master, she was ill.

(Drs. Berg and Minch) and 1994 (Drs. Burd and Drachman), which support petitioner's claim that the symptoms began in 1992.

All this evidence was shunned by the Special Master on the strength of language that he took from the first page of Dr. Ginsberg's letter – language that the Special Master then used in arbitrarily favoring the Ginsberg letter as an earlier-in-time account that contradicted later recordations. It remains for the Special Master, on remand, to consider the record as a whole in light, *inter alia*, of the second page of the Ginsberg letter. And, depending upon the circumstances, of course, it may also prove necessary for the Special Master to determine whether petitioner has met her burden on all three of the so-called *Althen* factors.[14] In fact, the Special Master did a much more comprehensive review of these factors in rejecting petitioner's SLE claim. It is to the review of those findings that the court now turns.

(2) SLE

The Special Master's review of petitioner's SLE claim was much different than his approach to her hypothyroidism claim. To recap, the Special Master held that petitioner's onset of her SLE symptoms occurred well after the administration of the vaccinations and outside what the Special Master deemed a medically appropriate time frame would be for the vaccine to have been the cause.

Under what is commonly referred to as *Althen*'s third prong, a vaccine claimant is obliged to show a "proximate temporal relationship between the vaccination and the injury." *Althen*, 418 F.3d at 1278. This required petitioner to provide "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health and Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008); *see also Pafford v. Sec'y of Health and Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006) ("Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis."); *Doyle ex rel. Doyle v. Sec'y of Health and Human Servs.*, 92 Fed. Cl. 1, 6 (2010). Under this test, petitioner was first required to establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the SLE was caused by the vaccination. Then, she was obliged to show that the onset of her SLE

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[14] When a petitioner has suffered an off-Table injury, *Althen* requires him or her to:

> show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278.

occurred during this causation period. *See de Bazan*, 539 F.3d at 1352 (stating, "we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late"); *Campbell v. Sec'y of Health and Human Servs.*, 97 Fed. Cl. 650, 671 (2011).

"As *de Bazan* indicates, the 'etiology' of the disorder determines the appropriate temporal relationship." *Veryzer v. Sec'y of Health and Human Servs.*, 2011 WL 4888776, at *12 (Fed. Cl., Sept. 29, 2011) (quoting *de Bazan*, 539 F.3d at 1352). Here, the Special Master found that the average expected time within which a patient might begin to display SLE symptoms is between two to three weeks after the administration of the hepatitis-B vaccination. In so concluding, the Special Master relied upon testimony from petitioner's main expert, Dr. Shoenfeld, who had published a peer-reviewed paper documenting the cases of five healthy patients who developed SLE within three weeks of immunization. *Shapiro*, 2011 WL 1897650, at *14. The Special Master noted that respondent's main expert, Dr. Ward, had not contradicted this time frame and that petitioner's other proposed time frames – six to eight months and ten years – were not supported by the record. *Id*. The Special Master went on to examine petitioner's medical records to see if she developed symptoms of SLE within three weeks of the dates of the second and third vaccine doses, September 21, 1992, and February 8, 1993, respectively. *Id*. The Special Master found that the two symptoms that Dr. Shoenfeld identified with petitioner's onset of SLE – joint pains and the hematuria – did not appear during the medically appropriate interval. *Id*. at *15. Rather, the Special Master found that the record revealed that Ms. Shapiro did not report these symptoms until July of 1993, more than five months after receiving the third dose of the vaccine. *Id*. Accordingly, he concluded that petitioner had failed to demonstrate the development of SLE within the medically appropriate interval. *Id*. at 15-16.

The denial of compensation in this case as to petitioner's SLE claim was not the result of a misapplication of the law, but rather the shortcoming in petitioner's evidence. Simply put, as the Special Master explained in his findings, petitioner failed to demonstrate that she had SLE symptoms during the accepted temporal causation period; rather, it appears that her SLE symptoms manifested themselves months after she received her second vaccination. So long as the "Special Master's conclusion [is] based on evidence in the record that [is] not wholly implausible, [the Court is] compelled to uphold that finding as not being arbitrary or capricious." *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1363 (Fed. Cir. 2000)). And that is the case here. Unlike the Special Master's consideration of petitioner's hypothyroidism claim, the denial of her SLE claim was based on the Special Master's weighing of the evidence. Laid bare, petitioner's arguments reflect little more than mere disagreement with the finding that petitioner failed to establish a proximate temporal relationship between the vaccination and the onset of the SLE. "'Such naked claims,'" this court has stated, "'by all appearances unsupported by anything in the record, fall far short of meeting the heavy burden of demonstrating that these findings were the product of an irrational process and hence arbitrary and capricious.'" *Doyle*, 92 Fed. Cl. at 7 (quoting *JWK Int'l Corp. v. United States*, 52 Fed. Cl. 650, 660 (2002), *aff'd*, 56

Fed. Appx. 474 (Fed. Cir. 2003)). Accordingly, the court sustains the Special Master's findings in this regard.[15]

III. CONCLUSION

This court need go no further. For the foregoing reasons, the court finds that the Special Master acted in an arbitrary and capricious fashion in rendering his decision as to petitioner's hypothyroidism claim, but acted appropriately in rejecting her SLE claim. Petitioner's motion for review, therefore, is **GRANTED**, in part, and **DENIED**, in part. The Special Master's Entitlement Decision of April 27, 2011, is hereby **VACATED**, in part, as indicated, and this matter is **REMANDED** to the Office of Special Masters for further proceedings consistent with this opinion. Pursuant to Vaccine Rule 28, the period of this remand shall not exceed 90 days.[16]

IT IS SO ORDERED.

s/ Francis M. Allegra
Francis M. Allegra
Judge

[15] Petitioner would have this court overturn the Special Master's findings based primarily on the contrary conclusion of its undoubtedly qualified expert, Dr. Shoenfeld. However, "proof of causation entails more than having a well-qualified expert proclaim that the vaccination caused a disease." *Doyle*, 92 Fed. Cl. at 8. At oral argument, petitioner also noted that some of the hypothyroidism symptoms that she experienced shortly after receiving the vaccines were also manifestations of her SLE. But, the Special Master found that these symptoms were attributable solely to her thyroid condition (or the treatment thereof) because, *inter alia*, they abated once petitioner was administered the proper dosage of Synthroid. *Shapiro*, 2011 WL 1897650, at *15. This finding is supported by the record (particularly, by the testimony of Dr. Ward) and the court sees no basis upon which to disturb it.

[16] This opinion shall be unsealed, as issued, after November 14, 2011, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.